K130657

510(k) Summary

JUL 15 2013

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: ___05/13/2013___

1. Submitter:

Name:	Allmedicus Co., Ltd, No. 7608 Dongil-techno town 7th, 823 Gwanyang 2-dong, Dongan-gu Anyang, Gyeonggi-do, Republic of Korea 431-062
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2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
1515 E. Katella Ave. Unit 2115,
Anaheim, CA 92805
Phone: 714-202-5789 Fax: 714-409-3357
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3. Device:

Proprietary Name:	LinkDr 2.0 Diabetes Management Software
Common Name:	Data Management Software
Classification Name:	Glucose test system Calculator / Data processing module for clinical use
Classification:	Class II, 21CFR 862.1345 21CFR 862.2110
Classification Product Code:	NBW, JQP

4. Predicate Device:

IN TOUCH® Diabetes Management Software (k984527) by LIFESCAN, INC.

5. Device Description:

The LinkDr 2.0 Diabetes Management Software is optional data management software for use with All Medicus brand blood glucose meters: GlucoDr Supersensor(K050985), GlucoDr Plus(K082328), and GlucoDr auto(K083628). The subject device consists of a LinkDr USB cable and software (provided in a CD). The LinkDr 2.0 Diabetes Management Software allows the transfer of data from the mentioned blood glucose meters to a personal computer (PC) for enhanced data management using graphic displays and analysis tools.

6. Intended Use:

The LinkDr 2.0 Diabetes Management Software is a PC-based software intended for use in home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for effective diabetes management. It is intended for use as an accessory to compatible All Medicus brand blood glucose monitoring systems such as the GlucoDr Supersensor blood glucose meter, GlucoDr Plus blood glucose meter and GlucoDr auto blood glucose meter.

7. Performance Data(Non-Clinical):

All Medicus Co, Ltd. conducted bench testing to demonstrate data accuracy transmission for each meter. Meter flags/functions were tested such as control solution, post- meal, pre-meal, exercise and stress to verify the information properly downloads from the meters to the data management software. Memory data rollover was also tested by adding five (5) data points to meters that were pre-loaded with full memory. Test results show that all glucose values, flags, data, and time properly downloaded from the meters to the software. Memory data rollover also functioned properly where the new glucose values replaced the oldest glucose values.

In addition, a study intended to assess personal lay users and professional healthcare users in the setup and use of the LinkDr 2.0 Diabetes Management Software was conducted. Overall, they rated the LinkDr 2.0 Diabetes Management Software at 100% for overall program as easy or somewhat easy. There were no users that rated the software program as somewhat difficult or difficult. 100% of them also responded that they are satisfied with the LinkDr 2.0 Diabetes Management Software and its manual.

The study results supports that the LinkDr 2.0 Diabetes Management Software is effective and provides accurate data management system as other predicate devices in the market.

8. Substantial Equivalence

Both management software programs can be described as follows:

- have the same intended use
- an optional software accessory for use with blood glucose monitors with data management capability.
- data transferred from the meter cannot be hanged or modified in any way.

There are some minor differences between the subject device and the predicate device in transmission port, software operation options, settings and some other features, but it does not constitute a new intended use. Despite the differences, the validation testing results presented in this 510K supports that the LinkDr 2.0 Diabetes Management Software is safe and effective as the predicate device.

9. Conclusion:

Based on the testing results, All Medicus Co, Ltd concludes that the LinkDr 2.0 Diabetes Management Software is safe and effective also, substantially equivalent to predicate device, LifeScan IN TOUCH® Diabetes Management Software (k984527).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 15, 2013

All Medicus Co., Ltd.
c/o Priscilla Chung
c/o LK Consulting Group USA, Inc.
1515 E. Katella Ave., Unit 2115
ANAHEIM CA 92805

Re: K130657
Trade/Device Name: LinkDr 2.0 Diabetes Management Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, JQP
Dated: May 28, 2013
Received: June 4, 2013

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: _K130657_

Device Name: LinkDr 2.0 Diabetes Management Software

Indication for use:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (Part 21 CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiological Health (OIR)

Katherine Serrano -S

Division Sign-Off
Office of In Vitro Devices and Radiological Health

510(k) k130657